Food and Drug Administration, HHS

material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

- (c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:
- (1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.
- (2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32910, June 26, 1995]

§184.1317 Garlic and its derivatives.

- (a) Garlic is the fresh or dehydrated bulb or cloves obtained from *Allium sativum*, a genus of the lily family. Its derivatives include essential oils, oleoresins, and natural extractives obtained from garlic.
- (b) Garlic oil meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 132, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
- (c) Garlic and its derivatives are used as flavoring agents and adjuvants as defined in §170.3(o)(12) of this chapter.
- (d) The ingredients are used in food at levels not to exceed good manufacturing practice.
 - (e) [Reserved]
- (f) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§184.1318 Glucono delta-lactone.

- (a) Glucono delta-lactone ($C_6H_{10}O_6$, CAS Reg. No. 90–80–2), also called D-gluconic acid delta-lactone or D-glucono-1,5-lactone, is the cyclic 1,5-intramolecular ester of D-gluconic acid. It is prepared by direct crystallization from the aqueous solution of gluconic acid. Gluconic acid may be produced by the oxidation of D-glucose with bromine water, by the oxidation of D-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals, or by the oxidation of D-glucose with enzymes derived from these microorganisms.
- (b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 134, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

code_of_federal_regulations/

- (c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:
- (1) The ingredient is used as a curing and pickling agent as defined in §170.3(o)(5) of this chapter, leavening agent as defined in §170.3(o)(17) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and sequestrant as defined in §170.3(o)(26) of this chapter.
- (2) The ingredient is used at levels not to exceed current good manufacturing practice.
- (d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 33896, Sept. 24, 1986]